K082703

OCT 1 4 2008

VII. 510(k) Summary

A. Sponsor/Submitter:

Marine Polymer Technologies, Inc.
107 Water Street
Danvers, MA 01923
Phone: 781-270-3200
Fax: 781-270-1133

B. Contact Person

Sergio Finkielsztein
President
781-270-3200 x 13

C. Date of Submission: September 15, 2008

D. Trade (Brand) Name: mRDH™ Bandage

E. Common Name: Cellulosic compression bandage, liquid bandage

F. Classification: Class I § 880.5090

G. Classification Name: liquid bandage

H. Product Code: KMF

I. Predicate Devices: Marine Polymer Technologies, K002550 RDH Bandage™
Medafor, Inc. K013225 Traumadex with Hemadex Clotting Beads
CrossLink-D, Inc.K061722 Bloxx Rapid Clotting Agent

J. Intended Use:

mRDH™ Bandage is a trauma dressing intended for the temporary control of severely bleeding wounds such as surgical wounds (operative, postoperative, donor sites, dermatological, etc.) and traumatic injuries.

K. Device Description:

mRDH Bandage™ is a soft, white, sterile non-woven lyophilized pad of a cellulosic polymer isolated from microalgae (poly-N-acetylglucosamine). It is attached to x-ray detectable gauze and packaged in a sterile blister pack. mRDH Bandage™ is available as a 4in x 4in (10cm x 10cm) bandage.

L. Summary of Substantial Equivalence:

Marine Polymer Technologies has submitted information on indication for use, biocompatibility and performance characteristics to establish that mRDH™ Bandage is substantially equivalent to currently marketed predicate device. mRDH™ Bandage has essentially the same intended use as the predicate device. Results of scientific testing have ensured that all materials are biocompatible, no new adverse effects were introduced and physical properties are appropriate for the intended use.

VIII. 510(k) Certification

I, Sergio Finkielsztein, President of Marine Polymer Technologies, believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 4 2008

Marien Polymer Technologies
% Mr. Sergio Finkielsztein
President
107 Water Street
Danvers, Massachusetts 01923

Re: K082703
Trade/Device Name: mRDH Bandage™
Regulation Number: 21 CFR 880.5090
Regulation Name: Liquid bandage
Regulatory Class: I
Product Code: KMF
Dated: September 15, 2008
Received: September 16, 2008

Dear Mr. Finkielsztein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K082703

Indications for Use Statement

510(k) Number

Device Name: mRDH Bandage™

Indications for use:

mRDH Bandage™ is a trauma dressing intended for the temporary control of severely bleeding wounds such as surgical wounds (operative, postoperative, donor sites, dermatological, etc.) and traumatic injuries.

Prescription Use ___X__ AND/OR Over-The-Counter Use _____
(Per 21 CFR. 801Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082703